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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/565,023 | 07/18/2006 | Esa Suokas | 12808/29 | 9012 |
| 26646 7590 05/14/2008 KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004 | | | | |
| EXAMINER HORNBERGER, JENNIFER LEA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3734 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 05/14/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,023

Applicant(s)

SUOKAS ET AL.

Examiner

JENNIFER L. HORNBERGER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 6/28/2006
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 2-6, 8, 9, 11, 12, 14, 15-17, 19, 20, 23, and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 2 recites "the device has reduced modulus and increased elasticity" but fails to disclose with the kind of modulus (i.e. tensile modulus) and with respect to what the modulus is reduced and the elasticity is increased.
4. Regarding claim 3, the phrase "any derivative of these" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "any derivative of these"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).
5. Claim 25 recites the limitation "it is made by melt or solution processing technique and subsequent processing method." There is no prior antecedent basis for "it" in the claims.
6. Claim 27 provides for the use of a multifunctional device, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

Claim 27 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

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definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (EP 1157708) in view of Vogt et al. (US 2008/005878733).

Regarding claim 1, Fischer et al. disclose a multifunctional synthetic bioabsorbable device comprising: a synthetic bioabsorbable polymeric matrix, particles of an additive agent in the form of pharmacological agent (paragraph 7). Fischer et al. fail to disclose cavities induced around the particles of the additive agent dispersed in said synthetic bioabsorbable polymeric matrix, said cavities existing in said matrix as a result of mechanical processing of a mixture of the matrix and said particles. However, Vogt et al. disclose cavities encapsulating an additive agent (paragraphs 9 and 10). Therefore, it would have been obvious to one of ordinary skill in the art induce cavities around the additive agent of the device of Fischer et al. to provide for more reliable and consistent drug delivery in view of Vogt et al. (paragraphs 9 and 10)

Regarding claim 2, Fischer et al. in view of Vogt et al. disclose the claimed invention except for the shape of the cavities. It would have been an obvious matter of design choice to determine the shape of the cavities, since applicant has not disclosed

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that the shape solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with circular cavities.

Regarding claim 3, Fischer et al. disclose the device is a suture, fiber, thread, cord, or wire (paragraph 7).

Regarding claim 4, Fischer et al. disclose the device is a mesh (paragraph 18).

Regarding claim 5, Fischer et al. disclose the device is a mesh comprising fibers of differing bioabsorbable properties (paragraph 10).

Regarding claim 6, Fischer et al. disclose the mesh comprises bioabsorbable fibers and non-bioabsorbable fibers, or fibers of differing bioabsorption rates (paragraph 10).

Regarding claim 7, Fischer et al. disclose the additive agent is an antibiotic in that it inhibits bacterial growth (paragraph 7).

Regarding claim 8, Fischer et al. disclose the additive agent is an antibiotic in that it inhibits bacterial growth (paragraph 7).

Regarding claim 9, Fischer et al. disclose the additive agent is an antibiotic in that it inhibits bacterial growth (paragraph 7).

Regarding claim 10, Fischer et al. disclose the additive agent comprises 0.01 to 50 wt-% of the weight of the said multifunctional device (paragraph 16).

Regarding claim 11, Fischer et al. disclose the additive agent comprises 0.01 to 50 wt-% of the weight of the said multifunctional device (paragraph 16).

Regarding claim 12, Fischer et al. disclose the additive agent comprises 0.01 to 50 wt-% of the weight of the said multifunctional device (paragraph 16).

Regarding claim 13, Fischer et al. discloses the claimed invention except for said additive agent comprises 1-10 wt-% of the weight of the said multifunctional device.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to ascertain the effective minimum and maximum amounts of the additive agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 14, Fischer et al. discloses the claimed invention except for said additive agent comprises 1-10 wt-% of the weight of the said multifunctional device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to ascertain the effective minimum and maximum amounts of the additive agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 15, Fischer et al. discloses the claimed invention except for said additive agent comprises 1-10 wt-% of the weight of the said multifunctional device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to ascertain the effective minimum and maximum amounts of the additive agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 16, Fischer et al. discloses the said multifunctional device is monofilamentous in its structure (paragraph 7, In 41).

Regarding claim 17, Fischer et al. discloses the said multifunctional device is monofilamentous in its structure (paragraph 7, In 41).

Regarding claim 18, Fischer et al. discloses the said multifunctional device is monofilamentous in its structure (paragraph 7, In 41).

Regarding claim 19, Fischer et al. discloses the said multifunctional device is multifilamentous in its structure (paragraph 10).

Regarding claim 20, Fischer et al. discloses the said multifunctional device is multifilamentous in its structure (paragraph 10).

Regarding claim 21, Fischer et al. discloses the said multifunctional device is multifilamentous in its structure (paragraph 10).

Regarding claim 22, Fischer et al. disclose the said multifunctional device has a drug releasing function effective to inhibit bacterial attachment and biofilm formation (paragraph 7, line 43).

Regarding claim 23, Fischer et al. disclose the said multifunctional device has a drug releasing function effective to inhibit bacterial attachment and biofilm formation (paragraph 7, line 43).

Regarding claim 24, Fischer et al. disclose the said multifunctional device has a drug releasing function effective to inhibit bacterial attachment and biofilm formation (paragraph 7, line 43).

Regarding claim 25, Fischer et al. discloses it is made by melt or solution processing technique and subsequent processing method (paragraph 15).

Regarding claim 26, Fischer et al. discloses the subsequent processing method is fiber spinning (paragraph 15).

Regarding claim 27, Fischer et al. disclose sutures which are well known in the art to be used for wound closure (paragraph 11).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number

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is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L. H./
Examiner, Art Unit 3734

jlh
4/9/08

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731